

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

THE UNITED STATES OF AMERICA, and

THE STATES OF CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE, FLORIDA, GEORGIA,
HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA,
MARYLAND, MASSACHUSETTS, MICHIGAN,
MINNESOTA, MONTANA, NEVADA, NEW
HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW
YORK, NORTH CAROLINA, OKLAHOMA, RHODE
ISLAND, TENNESSEE, TEXAS, VERMONT,
VIRGINIA, and WASHINGTON; THE DISTRICT OF
COLUMBIA; THE COUNTY OF ALLEGHENY; and THE
CITIES OF CHICAGO, NEW YORK, and
PHILADELPHIA,

ex rel. JOEL STEVENS,

Plaintiffs,

-v-

ATRICURE, INC., ST. HELENA HOSPITAL, and
ADVENTIST HEALTH,

Defendants.

Civil No. 1:22-cv-284

Judge Michael R. Barrett

**RELATOR’S MEMORANDUM OF LAW IN OPPOSITION TO
ATRICURE’S MOTION TO DISMISS THE FOURTH AMENDED
COMPLAINT PURSUANT TO FED.R.CIV.P. 12(b)(6) AND 9(b)**

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Relator Joel Stevens (“Relator”) files this Opposition to Defendant AtriCure, Inc.’s (“AtriCure” or the “Company”) August 17, 2022 Motion to Dismiss Relator’s Fourth Amended Complaint (ECF No. 88; “Complaint” or “Compl.”). For the reasons set forth below, AtriCure’s motion should be denied in its entirety.

I. INTRODUCTION

The Fourth Amended Complaint properly sets forth causes of action as to all federal reimbursement claims tainted by AtriCure’s unlawful kickback scheme. Relator alleges that AtriCure engaged in an unlawful promotional scheme, in concert with Defendants Adventist, Inc. and St. Helena Hospital, involving the offer and payment of illegal remuneration to healthcare providers and institutions to induce purchases of AtriCure’s medical devices, in violation of the federal Anti-Kickback Statute (the “AKS”) and the False Claims Act (“FCA”).

The United States and Plaintiff States have previously prosecuted AtriCure for FCA and AKS violations resembling those alleged by Relators’ here. On February 1, 2010, AtriCure entered into a multimillion-dollar Settlement Agreement and a Corporate Integrity Agreement with the United States to resolve allegations that AtriCure engaged in an illegal promotional scheme which caused the submission of false claims for reimbursement for over 2,000 surgical procedures performed using AtriCure products. Compl. ¶¶ 83-88. AtriCure has received notice of Relator and original source Stevens’ allegations inasmuch as his Complaint documents a continuation of the unlawful scheme for which the Company was previously (and successfully) prosecuted by the Government.¹ If the larger scale of AtriCure’s renewed kickback scheme

¹ The allegations resolved by the 2010 Settlement included that, between 2005 and 2008, “AtriCure caused false claims to be submitted by knowingly inducing hospitals to purchase its Ablation Devices by providing free or discounted marketing services and loaning or selling generators and disposable equipment to hospitals at less than fair market value.” Compl. ¶¶ 85-86.

requires Relator to provide more notice to the Company than its intimacy with the original scheme resolved in 2010 already provides, Relator pleads more than enough information to provide AtriCure with such notice, and to state cognizable claims against the Company under the applicable legal standards in the Sixth Circuit.

II. ARGUMENT

“In assessing a motion to dismiss under Rule 12(b)(6), [a] court construes the complaint in the light most favorable to the plaintiff, accepts the plaintiff’s factual allegations as true, and determines whether the complaint ‘contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.’” *Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 403 (6th Cir. 2012) (*quoting Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)) (second alteration in original). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. The factual allegations of a pleading “must be enough to raise a right to relief above the speculative level.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

The False Claims Act, 31 U.S.C. § 3729 *et seq.* (“FCA”), “is an anti-fraud statute that prohibits the knowing submission of false or fraudulent claims to the federal government.” *United States ex rel. Bledsoe v. Community Health Sys., Inc.*, 501 F.3d 493, 502-503 (6th Cir. 2007). The FCA creates civil liability for any person who “(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;” “(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;” or “(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G).” 31 U.S.C. § 3729(a)(1). As this Court has explained, “[t]o be eligible for payment under the

Medicare program, providers and suppliers must certify that they understand that payments of claims are conditioned on the claims and the underlying transactions complying with applicable laws, including the AKS.” *United States ex rel. Hallman v. Millennium Radiology, Inc.*, No. 1:11-cv-825, 2014 U.S. Dist. LEXIS 138549, 2014 WL 4908275, at *9 (S.D. Ohio Sept. 30, 2014) (citations omitted).

“To prove a violation of the AKS, Relator must show: (1) remuneration offered or paid; (2) in order to induce the referral of government healthcare business; (3) done ‘knowingly and willfully.’ 42 U.S.C. § 1320a—7b(b)(2)(B).” *Millennium Radiology*, 2014 U.S. Dist. LEXIS 138549, at *10. As a result, many FCA cases turn on whether a Relator can show that what was offered or paid by Defendant(s) was “remuneration” within the meaning of the statute, and whether the remuneration was paid with an “intent to induce.”

A. Relator’s Complaint States a Claim for Relief Under the FCA

1. Relator sufficiently pleads that AtriCure’s Kickback Scheme Results in Illegal Remuneration to AtriCure’s Customers

As this Court has previously explained,

This Court has interpreted “remuneration” broadly as meaning “anything of value in any form whatsoever.” *United States v. The Health Alliance of Greater Cincinnati*, 1:03-CV-00167, 2008 U.S. Dist. LEXIS 102411, 2008 WL 5282139,*7 (S.D. Ohio Dec. 18, 2008). This Court has explained that “[t]he Anti-Kickback Statute uses the term ‘any remuneration,’ which suggests an expansive reading of the form of any kickback directly or indirectly, as opposed to a narrow reading.” *Id.* (citing 42 U.S.C. § 1320a-7b (b)(1 & 2)(A)).

Millennium Radiology, 2014 U.S. Dist. LEXIS 138549, at *10-11. One of the principal reasons for this broad definition is the ingenuity of bad actors in finding ways to get around any narrower prohibition: as this Court has also noted, “the Anti-Kickback statute was amended to add the term ‘remuneration’ when investigations showed kickbacks were taking the form of sham rentals for office space, rebates equal to the percentage of referral business, outright gifts of cars, TV’s,

and” – of particular relevance here – “prepaid vacations.” *United States ex. rel. Fry v. Health Alliance of Greater Cincinnati*, No. 1:03-CV-00167, 2008 U.S. Dist. LEXIS 102411, *22 (S.D. Ohio Dec. 18, 2008).

AtriCure contends that that the Complaint “describes ordinary—and essential—training, research, and educational initiatives.” *Memorandum in Support of [Defendant] AtriCure’s Motion To Dismiss the Fourth Amended Complaint* (“AtriCure Mem.”), ECF No. 91-1 at 23. But if offers no reason that all-expenses paid trips to Napa Valley, in the heart of California’s wine country – including airfare, meals, lodging, ground transportation, and a trip to the Silverado vineyards there – should not be considered “[some]thing of value in [some] form whatsoever.” If visiting Napa and its wineries had not value, the tourism industry and winery tours in Napa would not be as they are.

But AtriCure *did* offer and provide just such a trip to Dr. Sanjay Tripathi – *twice*, on December 5, 2014, and again, less than six months later, on May 27-28, 2015, *see* Compl. ¶¶ 238, 242-43 – including staying “in Napa at what AtriCure employee Kent Richards described as ‘a very nice boutique hotel,’ *viz.* the Andaz Napa at 1450 First Street in Napa, California” on at least the latter occasion, which also included an excursion to Silverado Vineyards, Compl. ¶¶ 242-43, which clearly has no educational purpose or value relevant to cardiology. Likewise, AtriCure provided hundreds of dollars in food, beverage, and lodging to Dr. Ganesh Kumpati over the course of 2014 and into 2015. *See* Compl. ¶¶ 248, 252.

And after the junkets just described, both Dr. Tripathi and Dr. Kumpati *were* able to repay those inducements by using tens of thousands of dollars’ worth of AtriCure’s products in Medicare-reimbursed procedures – and, in fact, did so, on at least December 18, 2014 (Compl.

¶¶ 239-41); May 22, 2015 (Compl. ¶¶ 249-50); August 26, 2015 (Compl. ¶ 245); October 6, 2015 (Compl. ¶ 246); and October 27, 2015 (Compl. ¶ 254).

Regardless of any so-called educational or product support contexts, AtriCure’s suggestion that food and drink, and all-expenses paid trips to Napa wineries, are “[no]thing of value” belies common sense and is an argument better suited for summary judgment, not a motion to dismiss – and is inappropriate even then, since a reasonable juror could easily conclude that these inducements, in fact, have value.

The Complaint also details widespread additional compensation to those capable of giving business to AtriCure – and **only** to those capable of giving it business – including thousands of dollars in sham “consulting fees” paid to doctors with the ability to steer business to AtriCure (Compl. ¶¶ 90-108), various promotional efforts given to doctors for free (Compl. ¶¶ 109-32), and the services of a billing consultant and her firm, Kathryn Barry & Associates, LLC (“KBA”) – also free, but only to doctors who use AtriCure products. (Compl. ¶¶ 133-45.) As with the free trips to Napa, these inducements have value to the doctors who used them; they are not “[no]thing of value.” And as with the food, travel, and hotel inducements, AtriCure’s argument is entirely premature – and should fail at summary judgment, since a reasonable jury could decide that these inducements have value.

Indeed, this Court has already held that even ***the mere opportunity to earn*** payment can be an inducement, because every business – even a small medical practice – needs business. “For example, this Court found that scheduling time for doctors to work at a hospital’s ‘heart station,’ whereby they are provided with a ‘stream of patients,’ was something of value since ‘[g]iving a person an opportunity to earn money may well be an inducement.’” *Millennium Radiology*, 2014

U.S. Dist. LEXIS 138549 at *11 (*quoting Health Alliance of Greater Cincinnati*, 2008 U.S. Dist. LEXIS 102411 at *21).

Likewise, here, the “opportunity to earn money” as a paid speaker “may well be an inducement,” *id.*, as well as free advertising is – an issue also discussed at length in *Millennium Radiology*, and likewise resolved in Relator’s favor. *Id.* at *10-14.

Even the issue of free practice support has been addressed by this Court, which found that these perquisites could have been offered as inducements, and thus, dismissal prior to discovery was inappropriate: “In another case, this Court found that ‘not having to do the work of the professional component of the test and not having to set up and maintain the infrastructure in order to do the test and, instead, merely reviewing work that is already complete and signing one’s name is,’ as every partner at a law firm knows, ‘certainly something of value.’” *Id.* at *11 (*quoting United States ex rel. Daugherty v. Bostwick Labs.*, 1:08-CV-00354, 2012 U.S. Dist. LEXIS 178641, 2012 WL 6593804, at *11 (S.D. Ohio Dec. 18, 2012)).

The same is true of AtriCure’s “grants” (*i.e.*, payments, Compl. ¶¶ 149-68) and other to inducements to institutions, including a \$50,000 cardiac mapping machine (Compl. ¶¶ 169-92, noting the dates and value of tens of thousands of dollars’ worth of AtriCure implants and other products being given to various institutions and individuals, including Porter Adventist and Dr. Tripathi) – all of which aid in “set[ting] up and maintain[ing] the infrastructure” of these institutions. *Millennium Radiology*, 2014 U.S. Dist. LEXIS 138549 at *11. And as with payments and other perks given to individual doctors, so these same payments and other perks given to institutions are forms of inducement.

Even apart from the obvious independent value of fungible items such as computer laptops (Comp. ¶ 175), the independent value of AtriCure’s capital equipment used “in

conjunction with” AtriCure’s disposable products is evidenced by the company’s efforts to conceal its gifting of such equipment by disguising it as legitimate “Loaner” agreements (Comp. ¶ 172-86). Had AtriCure’s customers’ loan commitments not been fictitious, the customers “would otherwise have had to cover the costs....thus lowering their profits per surgery.” *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 807-08 (S.D.N.Y. 2017) (citing *Ameritox, Ltd. v. Millennium Labs., Inc.*, 20 F. Supp. 3d 1348, 1356 (M.D. Fla. 2014)), *rev’d on other grounds*, *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163 (2d Cir. 2018). The discount safe harbor applies neither to loans not subject to any financial commitment by the borrower nor to remuneration in the form of “no-charge” disposable equipment (Compl. ¶¶ 187-92) inasmuch as the underlying discounts are not based on an arms-length, commercially reasonable transactions. *See* OIG Advisory Opinion No. 99-2 (Feb. 26, 1999).²

For all of these items and payments, there may be additional context that Defendants wish to provide, but none of that “context” means that Relator has failed to state a claim for inducing the submission of claims to Government healthcare programs – and, when that time comes, that context should be submitted to a jury, because it is all issues of fact, such that a reasonable jury could also determine that these various payments and other perks are, in fact, inducements.

As this Court has correctly observed, “[i]mportantly, under the anti-kickback statute, neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business).” *Millennium Radiology*, 2014 U.S. Dist. LEXIS 138549 at *11 (quoting *OIG*

² <https://oig.hhs.gov/documents/advisory-opinions/396/AO-99-02.html>. (last accessed October 5, 2022).

Supplemental Compliance Program Guidance for Hospitals, 70 Fed.Reg. 4858, 4864 (Jan. 31, 2005)).

2. Relator has Pleaded that at Least One “Purpose” of its Remuneration was to Induce Referrals

AtriCure cavalierly describes these inducements as “ordinary – and essential – training, research, and educational initiatives,” *AtriCure Mem.* at 23, but what the Complaint *actually* alleges is that “AtriCure’s illegal *inducements included cash payments* made to surgeons and EPs to utilize AtriCure devices and to appear on AtriCure’s behalf at promotional events for the ostensible purpose of providing or receiving educational information” Compl. ¶ 95 (emphasis supplied). This Court has rejected the argument that a relator “must plead facts negating plausible alternative motives” for a discounting arrangement in order to plead an intent to induce referrals. *Millennium Radiology*, 2014 U.S. District LEXIS 138549 at *18. Relator need only plead that *one purpose* of the remuneration was to induce referrals:

[T]he “Third, Fifth, Ninth, [Seventh], and Tenth Circuits” are in accord that “[n]othing in the Medicare fraud statute implies that only the primary motivation of remuneration is to be considered;” rather, “*if part of the payment* compensated past referrals or induced future referrals, that portion of the payment violates” the statute.

United States v. Se. Eye Specialists, PLLC, 570 F. Supp. 3d 561, 577 (M.D. Tenn. 2021) (emphasis supplied) (quoting *United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011)); *see also* OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed.Reg. 4858, 4864 (Jan. 31, 2005) (“Importantly, under the anti-kickback statute, neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business).”).

Further, the Complaint alleges particularized details, including that “Dr. Tripathi received at least \$1,877 in kickbacks from Defendant AtriCure,” including “\$825.46 worth of food, travel,

and lodging . . . *All of these payments were kickbacks in violation of the AKS.*” Compl. ¶ 238 (emphasis supplied). The Complaint goes on to allege that “[t]hese kickbacks had the desired effect,” Compl. ¶ 239, of inducing Dr. Tripathi to use AtriCure products in a procedure performed on a Medicare patient on December 18, 2014, *id.*, and names the parts used, their prices, and Lot/Serial Number, *id.* at ¶ 240, further alleging that their prices were “multiples more than the cost of AtriCure’s kickbacks to Dr. Tripathi that year, and thus an extremely positive return on AtriCure’s investment in its kickbacks paid to Dr. Tripathi.” *Id.* at ¶ 241.

After providing additional details and examples of further kickbacks and surgeries with Dr. Tripathi, the Complaint goes on to allege that “Dr. Kumpati likewise received a number of kickbacks from AtriCure,” and lists a number of example inducements, including \$921 in travel and lodging on August 12, 2014. *Id.* at ¶ 248. The Complaint goes on to allege, “*these inducements were effective*,” *id.* at ¶ 249 (emphasis supplied), and describes a procedure that Dr. Kumpati performed on a Medicare beneficiary, including the parts used, their prices, and Lot/Serial Number. *Id.* at ¶ 249-50. The Complaint then alleges that “[a]ll of these AtriCure products were billed to CMS for a total of at least \$19,790 – multiples more than the cost of AtriCure’s kickbacks to Dr. Kumpati the preceding year, and thus an extremely positive Return on Investment for AtriCure.” *Id.* at ¶ 251.

As with Dr. Tripathi, the Complaint then goes on to allege the details of additional inducements provided by AtriCure and another surgery performed by Dr. Kumpati that used AtriCure parts and resulted in claims being submitted to the Department of Veterans Affairs.

The foregoing, and the many other allegations of knowing inducement throughout the Complaint, are a more-than-sufficient basis upon which to find that the Relator has adequately alleged that AtriCure knowingly caused the submission of false claims, in violation of the AKS

and the FCA. But in this case, there is the additional allegation that AtriCure entered into a Corporate Integrity Agreement (“CIA”) in which it specifically promised to obey the AKS. Compl. ¶¶83-88. Thus, any violation of the AKS is, *per se*, intentional, or at the very least, an “aggravated form of gross negligence” or “reckless disregard” of AtriCure’s obligations to know and follow the law. The Complaint alleges that the CIA’s covered conduct specifically included kickback allegations: “that AtriCure caused false claims to be submitted by knowingly inducing hospitals to purchase its Ablation Devices by providing free or discounted marketing services and loaning or selling generators and disposable equipment to hospitals at less than fair market value.” Compl. ¶ 85 (citing 2010 Settlement Agreement, Section II.C.(3)). Further, the CIA required AtriCure:

to develop “appropriate ways to conduct Promotional and Product Services Related Functions ***in compliance***” with “all applicable FDA requirements, including FDA regulatory approval requirements,” as well as with “all applicable Federal healthcare program requirements, ***including, but not limited to, the Federal anti-kickback statute . . . and the False Claims Act.***”

Compl. ¶ 86 (citing CIA, Section III.B.2.b-c) (emphasis supplied).

For AtriCure to suggest that the inducements and kickbacks that it offered and paid, in violation of “the Federal anti-kickback statute . . . and the False Claims Act,” were somehow inadvertent or unknowing – ***when AtriCure had recently promised the Government that it would not violate exactly those two statutes*** – is disingenuous, at best; and, in any case, Relator has sufficiently alleged that AtriCure’s conduct more than met the “reckless disregard” standard necessary to state a claim under those statutes. Accordingly, Defendant’s motion should be denied.

3. Relator Adequately Pleads that AtriCure Acted with the Requisite Scienter

Relator must also prove that the Defendants “knowingly” violated the FCA when engaging in its illegal kickback scheme. This Court has held that while ““a violation of the [AKS] may be shown without establishing that the defendant(s) acted ‘with knowledge of illegality,’” *Millennium Radiology*, U.S. Dist. LEXIS 48214 at *20 (quoting *McDonnell v. Cardiothoracic & Vascular Surgical Associates, Inc.*, No. C2-03-79, 2004 U.S. Dist. LEXIS 29436, 2004 WL 3733402, *8 (S.D. Ohio, July 28, 2004), itself citing *United States v. Neufeld*, 908 F. Supp. 491, 497 (S.D. Ohio 1995)), “there must be an allegation that the defendant acted with the ‘purpose to commit a wrongful act.’” *Millennium Radiology*, U.S. Dist. LEXIS 48214 at *20 (quoting *McDonnell*, 2004 U.S. Dist. LEXIS 29436, [WL] at *8).

The Sixth Circuit has since further expounded upon those requirements, as follows:

“[A]n aggravated form of gross negligence (i.e., reckless disregard) will satisfy the *scienter* requirement for an FCA violation.” *United States ex rel. Wall v. Circle C Constr., L.L.C.*, 697 F.3d 345, 356 (6th Cir. 2012) (alteration in original) (quoting *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 945 n.12 (10th Cir. 2008)). Congress added the “reckless disregard” prong to the definition of knowledge in the False Claims Act “to target that defendant who has ‘buried his head in the sand’ and failed to make some inquiry into the claim’s validity.” *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 530 (6th Cir. 2012) (quoting S. Rep. 99-345, at 21 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5286). This inquiry must be “reasonable and prudent under the circumstances.” *Id.* (quoting S. Rep. 99-345, at 21 (1986), reprinted in 1986 U.S.C.C.A.N. at 5286)

United States ex rel. Lynch v. Univ. of Cincinnati Med. Ctr., LLC, No. 1:18-cv-587,, 2020 U.S. Dist. LEXIS 48214 at *96-97 (quoting *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 837 (6th Cir. 2018)).

Here, there can be no doubt that Relator’s Complaint meets this standard. For one thing, “at the motion-to-dismiss stage, a plaintiff need only allege the *scienter* element generally.” *Lynch*, 2020 U.S. Dist. LEXIS 48214 at *96 (quoting *Prather*, 892 F.3d at 837, itself citing *Fed.*

R. Civ. P. 9(b)). And Relator has more than adequately done so; his Complaint is replete with language indicating AtriCure's intent regarding its kickback programs. There are far too many instances, found throughout the Complaint, to list *in toto* here, but a few examples illustrate the point amply: "AtriCure's business model focuses largely on offering surgeons lucrative agreements **to induce** them to use AtriCure products when performing AFib procedures," Compl. ¶ 90 (emphasis supplied), including "us[ing] these agreements as vehicles to pay surgeons illegal kickbacks in the form of dinners, free attendance at conferences, free products, and remuneration for performing certain promotional-related activities," *id.* at ¶ 93. The Complaint also includes a table enumerating surgeons and EPs who "each promoted and/or performed procedures using AtriCure products on behalf of the company and each received a total of at least \$1,500 in their individual capacities from AtriCure between 2013 and 2018." *Id.* at ¶ 94.³

B. The Complaint Satisfies Rule 9(b)'s Particularity Requirement

Because both the FCA and AKS sound in fraud, any complaint must comply with the particularity requirements of Federal Rule of Civil Procedure ("Rule") 9(b), discussed at length, *infra*. As this Court has previously held, while alleging facts sufficient to infer the presentment of at least one claim is necessary to prosecute a case brought under the False Claims Act (whether *qui tam* or brought directly by the Government itself), and "[w]hile establishing 'personal knowledge' is one way to create an inference that a claim was submitted, **it is not the only means.**" *Lynch*, 2020 U.S. Dist. LEXIS 48214 at *91 (quoting *Millennium Radiology*, 2014

³ AtriCure's recitation of the current status of the Food and Drug Administration's approvals of its devices for use in certain surgeries (AtriCure Mem. at 25-28) provides it no quarter. The AKS's reach extends beyond any off-label billing to encompass *all* claims tainted by Defendants' alleged kickbacks. Compl. ¶¶ 32-40.

U.S. Dist. LEXIS 138549 at *24) (emphasis supplied). “If a relator alleges a widespread fraud, then ‘a single adequately pled claim of this nature would allow relators to satisfy Rule 9(b)’s pleading requirement and proceed to discovery on the entire scheme.” *United States ex rel. USN4U, LLC v. Wolf Creek Fed. Servs.*, 34 F.4th 507, 514 (6th Cir. May 16, 2022) (citing *United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 915 (6th Cir. 2017)).

As this court explained in *Lynch*, pleading additional factual details can suffice to meet the *Bledsoe* standard:

Relator has alleged facts strongly suggesting that “actual false claims [] in all likelihood exist” and have been presented to the Government for payment by [Defendant]. *See Bledsoe II*, 501 F.3d at 504 n.12. Relator has identified specific TAVR procedures performed at [medical center] during the relevant time period that were billed to the Government.

Lynch, 2020 U.S. Dist. LEXIS 48214, *88 (first alteration in original) (quoting *Bledsoe*, 501 F.3d at 510-11).

Nor is the *Lynch* court alone in its interpretation of the commands of the Sixth Circuit with respect to Fed. R. Civ. P. (“Rule”) 9(b). For example, in *Millennium Radiology* this court upheld a complaint, not only as to a Defendant where there were “aging reports show[ing] that [Defendant] submitted claims for payment to the government, the amounts submitted and the times submitted,” but also as to a second Defendant, not covered by the log, because the vast majority of this Defendant’s patients were treated at the first facility and because – as here – “[Relator] has identified . . . patients by their initials who underwent surgery on certain dates.” *Millennium Radiology*, U.S. Dist. LEXIS 48214 at *25.

As in *Lynch*, Relator here has made similarly detailed allegations, including identifying specific cardiac VATS/MAZE and other procedures, to “create a strong inference that [Defendant] presented or caused to be presented false claims for payment to the Government and

satisfy Relator's burden to plead his fraud claims against [Defendant] with particularity," *Lynch*, 2020 U.S. Dist. LEXIS 48214, at *89. In *Lynch*, the Relator "obtained a TAVR case log" that included:

the payment status for Drs. Shreenivas and Arif's TAVR patients by patient initials, medical record number, CPT Code (specifying a TAVR procedure), the date the TAVR procedure was performed, the "date posted," the specific invoice number, and the identity of the governmental insurance carrier (Medicare, VA, or CareSource).

Id. at *89-90. Here, Relator alleges similar details about the claims, including providing the date the procedure was performed (Compl. ¶¶ 239, 245-46, 249), the type of procedure (VATS/MAZE, Compl. ¶¶ 245-46), the hospital where it was performed (Compl. ¶¶ 245 (Porter Adventist), 246 (same), 249 (University of Utah Health), the identity of the governmental insurance carrier (Medicare, Compl. ¶¶ 245-46), and identifying information for the patient: date of birth, rather than initials. (Compl. ¶¶ 239, 245-46, 249). In addition, as discussed *supra*, Relator provides specific batch/lot numbers and/or prices of the materials billed for. (Compl. ¶¶ 240, 246, 250, 254).

Likewise, the decision in *Millennium Radiology* follows a similar analysis and compels a similar result. The *Millennium Radiology* Relator, Dr. Hallman, identified nineteen patients. While this is more than in the case at bar, so much of the record as is not under seal in that case suggests Dr. Hallman provided significantly less detail as to each patient, identifying them only by their initials and the date the surgery was performed. *Millennium Radiology*, 2014 U.S. Dist. LEXIS 138549 at *25. Here, while Relator has not provided initials, he has provided exact birthdates, procedure types, and specific parts either pre-authorized (¶ 254) or actually used (¶¶ 240, 250), including, for the latter, specific part/lot numbers (*id.*), and for all example surgeries, the prices AtriCure charged for those parts. ¶¶ 240, 250, 254.

Further, *Millennium Radiology* was decided in 2014, and the Court was thus without the benefit of the Sixth Circuit’s decision in *United States ex rel. Prather v. Brookdale Senior Living Cmtys, Inc.*, 838 F. 3d 750 (6th Cir. 2016), which-affirmed that

[Relator’s] allegations of personal knowledge of a detailed fraudulent scheme, including identification—based on her experience with billing-related matters—of specific false claims within that scheme and facts supporting a strong inference that those specific claims were submitted to the government for payment cannot be said to be improper conjecture.

Id. at 771. “Indeed,” the *Prather* court went on to note, “it could be said to be conjecture ‘only if we were willing to attribute to [the defendants] a highly unusual business model.’” *Id.* (quoting *United States ex rel. Clausen v. Labs. Corp. of Am.*, 290 F.3d 1301, 1317 (11th Cir. 2002) (Barkett, J., dissenting)). While the *Prather* court was referring to a highly unusual model⁴ that is distinct from the present case, here, the same logic applies: in order for claims tainted by kickbacks for the identified AtriCure products **not** to have been submitted, the hospitals where the surgeries were performed, and the doctors performing them, would have had to have followed an equally “highly unusual model,” one in which they did not seek reimbursement for their services.

Furthermore, it must be noted that in *Prather*, the claims as to which Ms. Prather had personal knowledge **had not been submitted** at the time that she worked on them, but were nevertheless considered as reliable indicia that claims had, in fact, later been submitted. Similarly, the various details that Relator has pled here are reliable indicia that claims were submitted for payment, including for the heart surgery at the George E. Wahlen Department of

⁴ *Viz.*, one “in which [Relator] and others were hired for a year-long project reviewing final Medicare claims in an attempt to avoid the recoupment of anticipated payments that were previously obtained, when in fact the defendants had never actually requested or received those anticipated payments.” *Prather*, 838 F.3d at 771-72.

Veterans Affairs Medical Center at 500 Foothill Boulevard, Salt Lake City, Utah, scheduled for October 27, 2015, and described in ¶ 254. There is nothing to suggest that this surgery was not, in fact performed on the scheduled date, but even if it had been delayed, it is not mere “conjecture” to conclude that this non-elective heart surgery was, in fact, performed, and a claim submitted to Tricare, since it is standard practice for claims to be submitted for all surgeries performed at Veterans’ Administration (“VA”) facilities. Additionally, it is reasonable to conclude that AtriCure’s free reimbursement consultant Ms. Barry educated Dr. Kumpati on August 18, 2015 on how to *ensure* that the expensive surgery scheduled on September 29, 2015 (Compl. ¶ 133-45; 253-54) would *in fact* be reimbursed by the VA program, without which assurance it is unlikely that Dr. Kumpati would have even scheduled the surgery. Under the Sixth Circuit’s most recent precedent concerning the Rule 9(b) standard in FCA cases (conspicuously not cited by AtriCure), even if this Court could “reasonably draw[] such an inference in either direction,” the inference should not be drawn in the Defendants’ favor.” *USN4U, LLC*, 34 F.4th at 514 n.2 (citing *Bickerstaff v. Lucarelli*, 830 F.3d 388, 396 (6th Cir. 2016)).

Further still, here, Relator provides additional factual details that support the strong inference “that ‘actual false claims [] in all likelihood exist’ and have been presented to the Government for payment” *Lynch*, 2020 U.S. Dist. LEXIS 48214, at *89. For example, ¶ 211 of the Complaint lays out an AtriCure spreadsheet that “explained to hospitals and physicians the manner in which the hybrid procedure **would be reimbursed by Medicare** and was intended to promote it over alternative treatment.” Compl. ¶ 211 (emphasis supplied). Like the e-mail chain regarding “Dr. Shreenivas’s failure to complete the OP note for billing purposes” in *Lynch*, here, AtriCure’s guide to Medicare billing “adds further support for the conclusion that

actual false claims in all likelihood were submitted to the Government for payment.” *Lynch*, 2020 U.S. Dist. LEXIS 48214, at *92. This document could have no other purpose than to help AtriCure in explaining to its customers how to bill Medicare – after all, AtriCure does not submit claims itself, so the only plausible explanation for AtriCure having taken the time and expense to create this spreadsheet is for the information therein to be used by its customers, to help them submit claims to Medicare for the VATS/MAZE procedures they performed.

Finally, “AtriCure paid for a third-party consultant to provide detailed billing assistance, *gratis* to Dr. Kumpati, to help him get paid for procedures where he used AtriCure products. The third-party consultant’s free services included assistance with the reimbursement of Medicare claims.” Compl. ¶ 253. The free services for AtriCure’s physician customers of this billing consultant, Ms. Barry, are discussed at length in the Complaint under the heading “Reimbursement Services.” *Id.* ¶¶ 133-45. Consistent with AtriCure’s interpretations of *Prather* and *United States ex rel. Hirt v. Walgreen Co.*, 846 F.3d 870, 881 (6th Cir. 2017), Ms. Barry’s services provided for free on behalf of AtriCure were “to review Medicare [and other insurance] claims documentation for the sole purpose of obtaining reimbursement.” AtriCure Mem. at 16.

C. Relators’ Conspiracy Claims and Claims on Behalf of Plaintiff States

Relators’ arguments in support of their claims pursuant to 32 U.S.C. §3729(a)(1)(C) and on behalf of the Plaintiff States are set forth in Relator’s *Memorandum of Law in Opposition to Defendant St. Helena’s and Defendant Adventist Health’s Motion to Dismiss the Fourth Amended Complaint*, filed contemporaneously *herewith* and incorporated by reference as if set forth in its entirety herein. Relator believes that repeating this discussion here would be duplicative and unnecessarily require judicial resources in reviewing the discussion a second time.

III. CONCLUSION

For the foregoing reasons, AtriCure's motion to dismiss should be denied in its entirety. In the alternative, Relator should be granted leave to amend a Fifth Amended Complaint, as none of Relator's prior complaints have been tested by a motion to dismiss.

Dated: October 5, 2022

Respectfully submitted,

/s/ Kelly Mulloy Myers

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CERTIFICATE OF SERVICE

I certify that on October 5, 2022, the foregoing was filed electronically via the Court's authorized electronic filing system. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

/s/ Kelly Mulloy Myers